

September 7, 2001

Robert Dinneen
Renewable Fuels Association
One Massachusetts Avenue, NW
Suite 820
Washington, DC 20001

Dear Mr. Dinneen:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Ethanol, posted on the ChemRTK Web Site on, April 20, 2001. I commend the Ethanol HPV Challenge Consortium for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the information necessary to adequately characterize each SIDS endpoint. On its Chemical RTK HPV Challenge Program website EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

The sponsor, the Ethanol HPV Challenge Consortium, has provided data that satisfy the required SIDS endpoints. Although some deficiencies were noted, EPA is not recommending additional work at the SIDS level because of the weight of the evidence and the availability of an extensive database on ethanol.

EPA will post this letter and the attached Comments on the Chemical RTK web site within the next few days.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit general questions about the HPV Challenge Program through the Chemical RTK web site comment button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

**EPA Comments on Chemical RTK HPV Challenge Submission:
ETHANOL**

SUMMARY OF EPA COMMENTS

The sponsor, the Ethanol HPV Challenge Consortium, submitted a Test Plan and Robust Summaries to EPA, received March 30, 2001, for Ethanol (CAS # 64-17-5). EPA posted the submission on the RTK HPV Challenge Web site on April 20, 2001.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical and Environmental Fate Data: All appropriate SIDS level tests have been performed and adequate robust summaries have been submitted.
2. Health Effects Endpoints: All appropriate SIDS level tests have been performed. Although several deficiencies in repeated dose toxicity study summaries exist, availability of an extensive database on ethanol toxicity to experimental animals and the well-characterized toxic effects of alcohol on humans support the preceding statement. EPA believes that no additional testing is required at the SIDS level. Comments on robust summaries appear below.
3. Ecotoxicity: All appropriate SIDS level tests have been performed. Comments on robust summaries appear below.

EPA COMMENTS ON THE ETHANOL CHALLENGE SUBMISSION

Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

Adequate existing data are available for these endpoints.

Fate (photodegradation, stability in water, biodegradation, and transport/distribution).

Adequate existing data are available for these endpoints.

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Adequate existing data are available for these endpoints.

Ecological Effects.

Adequate existing data are available for these endpoints.

Test Plan Section 3, Ecotoxicity, c. Acute toxicity to aquatic plants has the following typographical errors:

- 1) line two, change . . .six species of aquatic invertebrates. . .to six species of aquatic plants. . . 2)
Ceriodaphnia is listed incorrectly under the aquatic plants section.

SPECIFIC COMMENTS ON ROBUST SUMMARIES

Health Effects

Repeated Dose Toxicity: Although the rationale for no additional repeated-dose toxicity testing appears reasonable, it is not well supported by the limited information provided in the six robust summaries for repeated-dose toxicity studies. Only two studies evaluated more than one dose level; and in those cases, the investigators could not accurately confirm the dose levels. In addition, no NOAEL was achieved and no clinical pathology parameters were evaluated in one study; in the second study, no concurrent control was used, limited clinical pathology was evaluated, and only males were tested. In the remaining four studies, ethanol was the control group for studies of urethane toxicity. Considering both the availability of an extensive database on ethanol toxicity to experimental animals and the well-characterized toxic effects of alcohol on humans, EPA believes that no additional testing is required at the SIDS level.

Ecological Effects

Among the several submitted study summaries, two 96-hr LC₅₀ fish toxicity studies (Mattson et al. 1976 and Johnson and Finley 1980), two 48-hr LC₅₀ aquatic invertebrate toxicity studies (Takahashi et al., 1987), and two 96-hr ErC₅₀ aquatic plant studies (El Jay 1996) were deemed adequate.

Followup Activity

None.